K081142
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510(K) SUMMARY

MAY 16 2008

1. SUBMITTER:

Scandimed International
DK 2600 Glostrup
Denmark
Establishment Registration Number: 3003376126
Official contact: Mr. Salah Chami, CEO
Telephone: 011-45-4492-6444
Date Prepared: April 16, 2008

2. DEVICE:

Tradename:	Auto-Band Ligator
Classification Name:	Hemorrhoidal Ligator
Classification:	Class II
Product Code:	78 MND
Regulation Number:	876.4400
Classification Panel:	Gastroenterology

3. PREDICATE DEVICE:

This Special 510(k) Premarket Notification is being submitted for a material change from latex ligation bands to latex free ligation bands. The predicate device used to determine substantial equivalence for this device was the Scandimed International Auto-Band Ligator (#K031236).

4. DEVICE DESCRIPTION:

The Scandimed Auto-Band Ligator consists of a ligator wheel head mounted on a scope fixation arm and connected by a stainless steel thread to the band barrel.

The only change being proposed in this current Special 510(k) Premarket Notification is to convert the original latex rubber ligating bands to latex free rubber ligating bands.

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The Auto-Band Ligator incorporates the following product features:

- Automatic Reverse Movement to START position after each release
- Snap Fixation system ensures stable fixation on the scope
- Adjustable Snap Fixation System facilitates fixation on all brands of scopes
- Precision One-Step Release Mechanism of bands
- Only a single band can be released at a time
- Latex Free Rubber Bands
- Available in 5, 7 or 10 band configurations

5. INTENDED USE:

The Auto Band Ligator is used to band esophageal varices or hemorrhoids in the colon. For single use only.

6. INDICATIONS FOR USE:

The Auto Band Ligator is used to band esophageal varices or hemorrhoids in the colon. For single use only.

7. COMPARISON OF CHARACTERISTICS:

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics and packaging are identical or substantially equivalent to the currently marketed predicate devices.

8. PERFORMANCE DATA:

The Auto-Band Ligator was subjected to relevant performance testing. The results of the performance testing demonstrated the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2008

SCANDIMED International
c/o Mr. Stephen M. Page
MedReg Associates, Inc.
29 Frigate Street
JAMESTOWN RI 02835

Re: K081142
Trade/Device Name: Auto-Band Ligator
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: MND
Dated: April 16, 2008
Received: April 22, 2008

Dear Mr. Page:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K081142

Device Name: Auto-Band Ligator

Indications for Use:

The Auto Band Ligator is used to band esophageal varices or hemorrhoids in the colon.

For single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081142